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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,501	12/31/2003	Mark S. Scheib	51644/AW/W112	1810

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/750,501	SCHEIB, MARK S.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-15-06.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Parent case now USPN 6,733,499. This must be amended into the specification section entitled "Cross-reference to related application". Currently the specification only lists the parent case application number (10/118,680).

The action is non-final. RCE filed 11-15-06. Terminal Disclaimer filed 9-14-06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16, 19-22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Stewart et al. (2002/0111,618).

Stewart discloses a method of ablating inner circumferences of pulmonary veins (PV) using a catheter (fig. 6; 132) with a circular ablation assembly (fig. 8; 190), shape memory material (Nitinol), a cylindrical tip electrode (194), and a generally straight distal region extending substantially tangentially from a generally circular curve (see distal elements in figures 13a, 16b, 17b, 17c, 19, 20b, 22, 25). The Office maintains that each of the distal elements in the listed figures read upon the Applicant's structure being

described as "a generally straight distal region extending substantially tangentially from a generally circular curve" and seen in Applicant's figure 5 element (extension) 40.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 17-20, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart (2002/0111,618) in view of Bowe et al. (6,771,996).

Stewart neglects to disclose dimensions. However, superior parameters/dimensions concerning the curve of the ablation assembly (190, figure 8, *inter alia*) could be determined via routine experimentation in light of Stewart. Under the supposition that the Applicant has claimed superior parameters/dimensions, Stewart thereby makes obvious these limitations. Further, for a singular generally circular curve see figures 6 and 7. Specifically regarding claim 16, the Examiner contends that rotating the device creating a "second position" and subsequently ablating would have been an obvious method step. Most surgeries require surgeons to apply energy more than once and to apply that energy using different configurations/positions of the device. Rotation is obvious in light of the symmetrical lesion depicted in figures 6 and 7. Without rotation of the Stewart ablation assembly, the symmetrical lesion is not feasible. This observation makes rotation obvious in order to create the lesion in figures 2c and 2d.

Furthermore, the obvious rotating step can only be done clockwise or counterclockwise, which correspond to pulling or pushing the tip electrode. The optimal of the (only) two choices would be determined through routine experimentation. This is certainly no cognitive leap warranting patentability.

Obviating any need to take "Official Notice" another reference with analogous art expressly disclosing rotation is presented. Bowe 6,771,996 discloses ablation of a circumferential band defined (col. 10:22-27) as a **continuous** line traced around a region of space and which starts and ends at substantially the same location. Bowe's embodiment in figure 8, as do many of the Stewart embodiments, depicts a **discontinuous** circular array of electrodes. The Office respectfully posits that rotation of the Bowe embodiment in figure 8, as well as the many similar embodiments in Stewart, **requires** rotation in order to create ablation of a circumferential band (which is defined as **continuous**).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Stewart in view of Bowe by determining dimensions as well as method steps through routine experimentation. The motivation would be to create a symmetrical lesion seen in Stewart figures 2c and figures 2d, by rotating the device.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart (2002/0111,618) in view of Bowe et al. (6,771,996) and further in view of Webster, Jr. (5,836,875).

Stewart and Bowe are silent concerning safety wires.

Webster discloses in an analogous electrode catheter, safety wires (figure 16 elements 48 and 49, claim 5).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Stewart in view of Bowe and further in view of Webster, Jr. by including a safety wire. The motivation would be prevent electrodes from falling off in the body.

Response to Arguments

Applicant's arguments filed 11-15-06 (RCE) have been fully considered but they are not persuasive. (Prior 102 rejections involving Stewart, Koblish and Bowe are obviated through the most recent amendment.) New Stewart art is presented to address the amendment. Webster, Jr. is also presented to show safety wires (figure 16 elements 48 and 49).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hall et al. (6,652,517), col. 2:50-55 discloses rotation of an ablation device with discontinuous electrodes as seen in Bowe figure 8 for a circumferential lesion.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
January 2, 2007




ROY D. GIBSON
PRIMARY EXAMINER